Complete Summary

GUIDELINE TITLE

Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Mar. 21 p. (Clinical guideline; no. 63).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Gestational diabetes mellitus
- Diabetic complications
- Pregnancy

GUIDELINE CATEGORY

Counseling
Evaluation

Management
Screening

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

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- To provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness
- To provide guidance on:
    - Preconception information
    - Diagnosis and management of gestational diabetes
    - Glycaemic control in the preconception, antenatal and intrapartum periods
    - Changes to medications for diabetes and its complications before or during pregnancy
    - Management of diabetic emergencies (for example, hypoglycaemia and ketoacidosis) and diabetic complications (such as retinopathy) during pregnancy
    - The timetable of antenatal appointments to be offered to women with diabetes
    - Timing and mode of birth (including induction of labour, caesarean section, analgesia and anaesthesia, and the use of steroids for fetal lung maturation)
    - Initial care of the newborn baby
    - Management of diabetes and its complications during the postnatal period

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TARGET POPULATION

Women with diabetes who are planning to become pregnant, who are already pregnant, and their newborn babies

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment/Screening

1. Assessment of risk factors
2. Screening for gestational diabetes (oral glucose tolerance test)
3. Establishing target blood glucose levels
4. Monitoring of blood glucose and ketone levels
5. Instructions for self monitoring of blood glucose
6. Retinal assessment
7. Renal assessment
8. Screening for congenital malformations
9. Monitoring fetal growth and well-being (ultrasound, amniotic fluid volume assessment)

Management/Treatment

1. Provision of information, advice and support to women who are pregnant or planning pregnancy
2. Lifestyle modifications (diet, dietary supplements, body weight and exercise)
3. Ensuring safety of medications (diabetes medications or diabetic complication medications)
4. Referral to joint diabetes antenatal clinic
5. Self management programmes
6. Hypoglycemic agents
7. Insulin therapy
8. Insulin analogues (aspart, lispro)
9. Concentrated glucose solution (in women with insulin-treated diabetes)
10. Glucagon (for women with type I diabetes)
11. Subcutaneous insulin infusion (as indicated)
12. Admission to critical care unit for suspected diabetic ketoacidosis
13. Thromboprophylaxis (for proteinuria)
14. Management of preterm labour
15. Intrapartum care
    - Timing and mode of birth
    - Analgesia and anaesthesia
    - Glycemic control (intravenous dextrose, insulin infusion)
16. Neonatal care (birth at hospital with neonatal resuscitation skills, criteria for neonatal unit admission)
    - Prevention and assessment of neonatal hypoglycemia
17. Postnatal care (breastfeeding, follow-up, contraception advice)Â

MAJOR OUTCOMES CONSIDERED

- Neonatal outcomes
    - Miscarriage, stillbirth, neonatal or infant death
    - Congenital malformation
    - Macrosomia, small for gestational age (SGA), low birthweight
    - Shoulder dystocia, birth trauma (bone fracture, nerve palsy)

        - Admission to intensive care unit, high-dependency unit, special care unit or transitional care unit
        - Hypoglycaemia, respiratory distress, sepsis, transient heart failure, resuscitation, jaundice, hypocalcaemia, polycythaemia, hypoxic ischaemic encephalopathy, impairment of neurodevelopment
- Maternal outcomes
    - Preterm birth
    - Mode of birth (spontaneous vaginal, instrumental, caesarean section)
    - Mode of infant feeding
    - Maternal health-related quality of life (validated questionnaire)
    - Maternal satisfaction with experience of pregnancy and birth
    - Perineal trauma, wound healing
    - Maternal death
    - Maternal obstetric complications (haemorrhage, infection, thrombosis, admission to intensive care unit, incontinence)
    - Maternal diabetic complications (glycaemic control [glycosylated haemoglobin; HbA1c], hypoglycaemic episodes, diabetic ketoacidosis [DKA], retinopathy, nephropathy, macrovascular disease)
    - Development of type 2 diabetesÂ

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Literature Search Strategy

Initial scoping searches were executed to identify relevant guidelines (local, national and international) produced by other development groups. The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Relevant published evidence to inform the guideline development process and answer the clinical questions was identified by systematic search strategies. The clinical questions are presented in Appendix B in the full guideline document. Additionally, stakeholder organisations were invited to submit evidence for consideration by the Guideline Development Group (GDG) provided it was relevant to the topics included in the scope and of equivalent or better quality than evidence identified by the search strategies.

Systematic searches to answer the clinical questions formulated and agreed by the GDG were executed using the following databases via the 'Ovid' platform: Medline (1966 onwards), Embase (1980 onwards), Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 onwards), and PsycINFO (1967 onwards). The most recent search conducted for the three Cochrane databases (Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects) was undertaken in Quarter 1, 2007. Searches to identify economic studies were undertaken using the above databases and the National Health Service (NHS) Economic Evaluation Database (NHS EED).

Search strategies combined relevant controlled vocabulary and natural language in an effort to balance sensitivity and specificity. Unless advised by the GDG, searches were not date specific. Language restrictions were not applied to searches, although publications in languages other than English were not appraised. Both generic and specially developed methodological search filters were used appropriately.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the databases was not undertaken.

Towards the end of the guideline development process, searches were updated and re-executed, thereby including evidence published and included in the databases up to 21 March 2007.

Evidence published after this date has not been included in the guideline. This date should be considered the starting point for searching for new evidence for future updates to this guideline. Further details of the search strategies, including the methodological filters employed, are provided on the CD-ROM accompanying the full version of the original guideline document (see "Availability of Companion Documents" field).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Intervention Studies

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

Levels of Evidence for Studies of the Accuracy of Diagnostic Tests

Ia: Systematic review (with homogeneity)[a] of level-1 studies[b]

Ib: Level-1 studies[b]

II: Level-2 studies[c]; systematic reviews of level-2 studies

III: Level-3 studies[d]; systematic reviews of level-3 studies

IV: Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or 'first principles'

[a] Homogeneity means there are no or minor variations in the directions and degrees of results between individual studies that are included in the systematic review.

[b] Level-1 studies are studies that use a blind comparison of the test with a validated reference standard (gold standard) in a sample of patients that reflects the population to whom the test would apply.

[c] Level-2 studies are studies that have only one of the following:

- Narrow population (the sample does not reflect the population to whom the test would apply)
- Use a poor reference standard (defined as that where the 'test' is included in the â□˜reference´, or where the 'testing' affects the 'reference')
- The comparison between the test and reference standard is not blind
- Case-control studies

[d] Level-3 studies are studies that have at least two or three of the features listed above.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

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Appraisal and Synthesis of Clinical Effectiveness Evidence

Evidence relating to clinical effectiveness was reviewed using established guides and classified using the established hierarchical system presented in "Rating Scheme for the Strength of the Evidence."Â This system reflects the susceptibility to bias that is inherent in particular study designs.

The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each study was assigned a quality rating coded as '++', '+' or '-'. For issues of therapy or treatment, the highest possible evidence level (EL) is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs; EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality were rated as '-'. Usually, studies rated as '-' should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of prognosis, the highest possible level of evidence is a cohort study (EL = 2). A level of evidence was assigned to each study appraised during the development of the guideline.

For each clinical question, the highest available level of evidence was selected. Where appropriate, for example, if a systematic review, meta-analysis or RCT existed in relation to a question, studies of a weaker design were not considered. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the effectiveness (accuracy) of the test was required, but where an evaluation of the effectiveness of the test in the clinical management of patients and the outcome of disease was required, evidence from RCTs or cohort studies was optimal. For studies evaluating the accuracy of a diagnostic test, sensitivity, specificity, positive predictive values (PPVs) and negative predictive values (NPVs) were calculated or quoted where possible (see Table 1.3 in the full version of the original guideline document).

The system described above covers studies of treatment effectiveness. However, it is less appropriate for studies reporting accuracy of diagnostic tests. In the absence of a validated ranking system for this type of test, NICE has developed a hierarchy of evidence that takes into account the various factors likely to affect the validity of these studies (see "Rating Scheme for the Strength of the Evidence").

Clinical evidence for individual studies was extracted into evidence tables (provided on the CD-ROM accompanying the full version of the original guideline) and a brief description of each study was included in the guideline text. The body of evidence identified for each clinical question was synthesised qualitatively in clinical evidence statements that accurately reflected the evidence. Quantitative

synthesis (meta-analysis) was not performed for this guideline because there were no clinical questions for which sufficient numbers of similar studies were identified to merit such analysis.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Expert Consensus (Nominal Group Technique)
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The NCC-WCH was commissioned by NICE to establish a multi-professional and lay working group (the Guideline Development Group [GDG]) to develop the guideline. The membership of the GDG was determined by the NCC-WCH and NICE, and included the following:

- Two obstetricians
- Two diabetes physicians
- Two diabetes specialist midwives
- A diabetes specialist nurse
- A general practitioner (GP)
- A neonatal paediatrician
- Two patient/carer representatives

Staff from the NCC-WCH provided methodological support for the guideline development process by undertaking systematic searches, retrieving and appraising the evidence, health economic modelling and writing successive drafts of the guideline. The neonatal paediatrician appointed to the GDG at the beginning of the development process resigned in October 2007 due to ill health and was replaced by another neonatal paediatrician.

During the development of the guideline, the GDG identified a need for expert advice in relation to obstetric analgesia and anaesthesia, diabetic retinopathy and data relating to pregnancy in women with pre-existing diabetes held by the Confidential Enquiry into Maternal and Child Health (CEMACH), which covers England, Wales and Northern Ireland. Expert advisers were appointed by the GDG to advise on each of these issues, although they were not involved in the final decisions regarding formulation of recommendations.

Organisations with interests in the management of diabetes and its complications from preconception to the postnatal period were encouraged to register as stakeholders for the guideline. Registered stakeholders were consulted throughout the guideline development process. The process of stakeholder registration was

managed by NICE. The different types of organisations that were eligible to register as stakeholders included:

- National patient and carer organisations that directly or indirectly represent the interests of women with diabetes and their families before and during pregnancy
- National organisations that represent the healthcare professionals who provide services for women with diabetes before and during pregnancy
- Companies that manufacture the preparations or products used in the management of diabetes in pregnancy
- Providers and commissioners of health services in England, Wales and Northern Ireland
- Statutory organisations such as the Department of Health and the Welsh Assembly Government
- Research organisations that have done nationally recognised research in relation to the topics covered in the guideline.

GDG Interpretation of the Evidence and Formulation of Recommendations

For each clinical question, recommendations for clinical care were derived using, and linked explicitly to, the evidence that supported them. In the first instance, informal consensus methods were used by the GDG to agree clinical and cost-effectiveness evidence statements. Statements summarising the GDG's interpretation of the evidence and any extrapolation from the evidence used to form recommendations were also prepared. In areas where no substantial clinical research evidence was identified, the GDG considered other evidence-based guidelines and consensus statements or used their collective experience to identify good practice. The health economics justification in areas of the guideline where the use of National Health Service (NHS) resources (interventions) was considered was based on GDG consensus in relation to the likely cost-effectiveness implications of the recommendations. The GDG also identified areas where evidence to answer their clinical questions was lacking and used this information to formulate recommendations for future research.

Towards the end of the guideline development process, formal consensus methods were used to consider all the clinical care recommendations and research recommendations that had been drafted previously. The GDG identified nine key priorities for implementation (key recommendations), which (in accordance with the criteria specified in the NICE guidelines manual) were those recommendations expected to have the biggest impact on care and outcomes for pregnant women with diabetes and their babies in the NHS as a whole. The key priorities were selected using a variant of the nominal group technique. Each GDG member submitted an electronic form indicating their top five recommendations in order of priority. The GDG members' votes were collated and a shortlist of priority recommendations was obtained by including all recommendations that had been voted for by at least one GDG member. The shortlisted recommendations were discussed at subsequent GDG meetings, and the final selection was made by retaining the recommendations that had received most votes and distilling the important issues contained in some long recommendations into more succinct recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Health Economics Considerations

The aims of the economic input to the guideline were to inform the Guideline Development Group (GDG) of potential economic issues relating to the management of diabetes and its complications from preconception to the postnatal period, and to ensure that recommendations represented cost-effective use of healthcare resources.

The GDG prioritised a number of clinical questions where it was thought that economic considerations would be particularly important in formulating recommendations. A systematic search for published economic evidence was undertaken for these questions. For economic evaluations, no standard system of grading the quality of evidence exists and included papers were assessed using a quality assessment checklist based on good practice in economic evaluation. Reviews of the very limited relevant published economic literature are presented alongside the clinical reviews or as part of appendices detailing original economic analyses (see below).

Health economic considerations were aided by original economic analysis undertaken as part of the development of the guideline where robust clinical effectiveness data were available and UK cost data could be obtained. For this guideline the areas prioritised for economic analysis were:

- Self-management programmes for women with diabetes who are planning a pregnancy (see Section 3.9 in the full version of the original guideline document)
- Treatment for gestational diabetes (see Section 4.3 in the full version of the original guideline document) – this was addressed through a unified analysis of screening, diagnosis and treatment for gestational diabetes involving joint work with the National Institute for Health and Clinical Excellence (NICE) antenatal care GDG
- Screening for congenital malformations (see Section 5.6 in the full version of the original guideline document)
- Monitoring fetal growth and wellbeing (see Section 5.7 in the full version of the original guideline document)
- Criteria for admission to a neonatal intensive care unit (NICU) or special care unit (see Section 7.1 in the full version of the original guideline document)

The results of each economic analysis are summarised briefly in the text of the full version of the original guideline. Detailed descriptions of the methods used for assessing the cost-effectiveness of self-management programmes are presented in Appendix C in the full version of the original guideline document. The methods used for assessing the cost-effectiveness of screening, diagnosis and treatment for gestational diabetes are presented in Appendix D and those for assessing the cost-effectiveness of screening for congenital cardiac malformations are described in Appendix E in the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations:

1. The first draft of the guideline (The full guideline, National Institute for Clinical Excellence [NICE] guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).
2. The final consultation draft of the full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Note from the Guideline Developer: In this reissued guidance, the information on the therapeutic indications, contraindications and use in pregnancy and lactation of drugs used in diabetes management and retinal assessment (specifically insulins, the oral hypoglycaemic agents metformin and glibenclamide, and tropicamide) has been corrected to follow the relevant Summary of Product Characteristics (SPCs) (July 2008). Changes have been made to the introduction and to relevant recommendations and footnotes.

Pre-conception Care

Outcomes and Risks for the Woman and Baby

Healthcare professionals should seek to empower women with diabetes to make the experience of pregnancy and childbirth a positive one by providing information, advice and support that will help to reduce the risks of adverse pregnancy outcomes for mother and baby.

Women with diabetes who are planning to become pregnant should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated.

Women with diabetes who are planning to become pregnant and their families should be offered information about how diabetes affects pregnancy and how pregnancy affects diabetes. The information should cover:

- The role of diet, body weight and exercise
- The risks of hypoglycaemia and hypoglycaemia unawareness during pregnancy
- How nausea and vomiting in pregnancy can affect glycaemic control
- The increased risk of having a baby who is large for gestational age, which increases the likelihood of birth trauma, induction of labour and caesarean section
- The need for assessment of diabetic retinopathy before and during pregnancy
- The need for assessment of diabetic nephropathy before pregnancy
- The importance of maternal glycaemic control during labour and birth and early feeding of the baby in order to reduce the risk of neonatal hypoglycaemia
- The possibility of transient morbidity in the baby during the neonatal period, which may require admission to the neonatal unit
- The risk of the baby developing obesity and/or diabetes in later life

The Importance of Planning Pregnancy and the Role of Contraception

The importance of avoiding unplanned pregnancy should be an essential component of diabetes education from adolescence for women with diabetes.

Women with diabetes who are planning to become pregnant should be advised:

- That the risks associated with pregnancies complicated by diabetes increase with the duration of diabetes
- To use contraception until good glycaemic control (assessed by HbA_{1c} [Note: Diabetes Control and Complications Trial (DCCT)-aligned haemoglobin A1c (HbA_{1c}) test]) has been established
- That glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy
- That additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers.

Diet, Dietary Supplements, Body Weight and Exercise

Women with diabetes who are planning to become pregnant should be offered individualised dietary advice.

Women with diabetes who are planning to become pregnant and who have a body mass index above 27 kg/m^2 should be offered advice on how to lose weight in line with the National Guideline Clearinghouse (NGC) summary of the National Institute for Health and Clinical Excellence (NICE) clinical guideline; noÂ 43 Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children.

Women with diabetes who are planning to become pregnant should be advised to take folic acid (5 mg/day) until 12 weeks of gestation to reduce the risk of having a baby with a neural tube defect.

Target Ranges for Blood Glucose in the Pre-conception Period

Individualised targets for self-monitoring of blood glucose should be agreed with women who have diabetes and are planning to become pregnant, taking into account the risk of hypoglycaemia.

If it is safely achievable, women with diabetes who are planning to become pregnant should aim to maintain their HbA_{1c} below 6.1%. Women should be reassured that any reduction in HbA_{1c} towards the target of 6.1% is likely to reduce the risk of congenital malformations.

Women with diabetes whose HbA_{1c} is above 10% should be strongly advised to avoid pregnancy.

Monitoring Blood Glucose and Ketones in the Pre-conception Period

Women with diabetes who are planning to become pregnant should be offered monthly measurement of HbA_{1c}.

Women with diabetes who are planning to become pregnant should be offered a meter for self-monitoring of blood glucose.

Women with diabetes who are planning to become pregnant and who require intensification of hypoglycaemic therapy should be advised to increase the frequency of self-monitoring of blood glucose to include fasting and a mixture of pre- and postprandial levels.

Women with type 1 diabetes who are planning to become pregnant should be offered ketone testing strips and advised to test for ketonuria or ketonaemia if they become hyperglycaemic or unwell.

The Safety of Medications for Diabetes before and during Pregnancy

Women with diabetes may be advised to use metformin as an adjunct to insulin in the pre-conception period and during pregnancy, when the likely benefits from improved glycaemic control outweigh the potential for harm. All other oral hypoglycaemic agents should be discontinued before pregnancy and insulin substituted. (Note: Metformin is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline [www.nice.org.uk/CG063fullguideline]. This evidence is not currently reflected in the Summary of Product Characteristics [SPC] [July 2008]. The SPC advises that when a patient plans to become pregnant and during pregnancy, diabetes should not be treated with metformin but insulin should be used to maintain blood glucose levels. Informed consent on the use of metformin in these situations should be obtained and documented.)

Healthcare professionals should be aware that data from clinical trials and other sources do not suggest that the rapid-acting insulin analogues (aspart and lispro) adversely affect the pregnancy or the health of the fetus or newborn baby.

Women with insulin-treated diabetes who are planning to become pregnant should be informed that there is insufficient evidence about the use of long-acting insulin analogues during pregnancy. Therefore, isophane insulin (also known as NPH insulin) remains the first choice for long-acting insulin during pregnancy.

The Safety of Medications for Diabetic Complications before and during Pregnancy

Angiotensin-converting enzyme inhibitors and angiotensin-II receptor antagonists should be discontinued before conception or as soon as pregnancy is confirmed. Alternative antihypertensive agents suitable for use during pregnancy should be substituted.

Statins should be discontinued before pregnancy or as soon as pregnancy is confirmed.

Removing Barriers to the Uptake of Pre-conception Care and When to Offer Information

Women with diabetes should be informed about the benefits of pre-conception glycaemic control at each contact with healthcare professionals, including their diabetes care team, from adolescence.

The intentions of women with diabetes regarding pregnancy and contraceptive use should be documented at each contact with their diabetes care team from adolescence.

Pre-conception care for women with diabetes should be given in a supportive environment and the woman´s partner or other family member should be encouraged to attend.

Self-Management Programmes

Women with diabetes who are planning to become pregnant should be offered a structured education programme as soon as possible if they have not already attended one (see â□˜Guidance on the use of patient-education models for diabetes´ [NICE technology appraisal guidance 60], available from www.nice.org.uk/TA060). (Note: â□˜Type 2 diabetes: the management of type 2 diabetes´ [NICE clinical guideline 66]), available from www.nice.org.uk/CG66, updates the information on type 2 diabetes in this technology appraisal).

Women with diabetes who are planning to become pregnant should be offered pre-conception care and advice before discontinuing contraception.

Retinal Assessment in the Pre-conception Period

Women with diabetes seeking pre-conception care should be offered retinal assessment as detailed in the next recommendation at their first appointment (unless an annual retinal assessment has occurred within the previous 6 months) and annually thereafter if no diabetic retinopathy is found.

Retinal assessment should be carried out by digital imaging with mydriasis using tropicamide, in line with the UK National Screening Committee´s recommendations for annual mydriatic two-field digital photographic screening as part of a systematic screening programme.

Women with diabetes who are planning to become pregnant should be advised to defer rapid optimisation of glycaemic control until after retinal assessment and treatment have been completed.

Renal Assessment in the Pre-conception Period

Women with diabetes should be offered a renal assessment, including a measure of microalbuminuria, before discontinuing contraception. If serum creatinine is abnormal (120 micromol/litre or more) or the estimated glomerular filtration rate (eGFR) is less than 45 ml/minute/1.73 m^2, referral to a nephrologist should be considered before discontinuing contraception.

Gestational Diabetes

Risk Factors for Gestational Diabetes

Healthcare professionals should be aware that the following have been shown to be independent risk factors for gestational diabetes:

- Body mass index above 30 kg/m^2
- Previous macrosomic baby weighing 4.5 kg or above
- Previous gestational diabetes
- Family history of diabetes (first-degree relative with diabetes)
- Family origin with a high prevalence of diabetes:
    - South Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh)
    - Black Caribbean
    - Middle Eastern (specifically women whose country of family origin is Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt)

Screening, Diagnosis and Treatment for Gestational Diabetes

The following three recommendations are taken from â□˜Antenatal care: routine care for the healthy pregnant woman´ (NICE clinical guideline 62), available from www.nice.org.uk/CG062.

Screening for gestational diabetes using risk factors is recommended in a healthy population. At the booking appointment, the following risk factors for gestational diabetes should be determined:

- Body mass index above 30 kg/m^2
- Previous macrosomic baby weighing 4.5 kg or above
- Previous gestational diabetes
- Family history of diabetes (first-degree relative with diabetes)
- Family origin with a high prevalence of diabetes:Â
    - South Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh)
    - Black Caribbean
    - Middle Eastern (specifically women whose country of family origin is Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt)

Women with any one of these risk factors should be offered testing for gestational diabetes (see recommendations below).

In order to make an informed decision about screening and testing for gestational diabetes, women should be informed that:

- In most women, gestational diabetes will respond to changes in diet and exercise
- Some women (between 10% and 20%) will need oral hypoglycaemic agents or insulin therapy if diet and exercise are not effective in controlling gestational diabetes
- If gestational diabetes is not detected and controlled there is a small risk of birth complications such as shoulder dystocia
- A diagnosis of gestational diabetes may lead to increased monitoring and interventions during both pregnancy and labour

Screening for gestational diabetes using fasting plasma glucose, random blood glucose, glucose challenge test and urinalysis for glucose should not be undertaken.

The 2-hour 75 g oral glucose tolerance test (OGTT) should be used to test for gestational diabetes and diagnosis made using the criteria defined by the World Health Organization. (Note: Fasting plasma venous glucose concentration greater than or equal to 7.0 mmol/litre or 2-hour plasma venous glucose concentration greater than or equal to 7.8 mmol/litre. World Health Organization Department of Noncommunicable Disease Surveillance [1999] Definition, diagnosis and classification of diabetes mellitus and its complications. Report of a WHO consultation. Part 1: diagnosis and classification of diabetes mellitus. Geneva: World Health Organization.) Women who have had gestational diabetes in a previous pregnancy should be offered early self-monitoring of blood glucose or an OGTT at 16–18 weeks, and a further OGTT at 28 weeks if the results are normal. Women with any of the other risk factors for gestational diabetes (see recommendation below) should be offered an OGTT at 24-28 weeks.

Women with gestational diabetes should be instructed in self-monitoring of blood glucose. Targets for blood glucose control should be determined in the same way as for women with pre-existing diabetes.

Women with gestational diabetes should be informed that good glycaemic control throughout pregnancy will reduce the risk of fetal macrosomia, trauma during

birth (to themselves and the baby), induction of labour or caesarean section, neonatal hypoglycaemia and perinatal death.

Women with gestational diabetes should be offered information covering:

- The role of diet, body weight and exercise
- The increased risk of having a baby who is large for gestational age, which increases the likelihood of birth trauma, induction of labour and caesarean section
- The importance of maternal glycaemic control during labour and birth and early feeding of the baby in order to reduce the risk of neonatal hypoglycaemia
- The possibility of transient morbidity in the baby during the neonatal period, which may require admission to the neonatal unit
- The risk of the baby developing obesity and/or diabetes in later life

Women with gestational diabetes should be advised to choose, where possible, carbohydrates from low glycaemic index sources, lean proteins including oily fish and a balance of polyunsaturated fats and monounsaturated fats.

Women with gestational diabetes whose pre-pregnancy body mass index was above 27 kg/m^2 should be advised to restrict calorie intake (to 25 kcal/kg/day or less) and to take moderate exercise (of at least 30 minutes daily).

Hypoglycaemic therapy should be considered for women with gestational diabetes if diet and exercise fail to maintain blood glucose targets during a period of 1–2 weeks.

Hypoglycaemic therapy should be considered for women with gestational diabetes if ultrasound investigation suggests incipient fetal macrosomia (abdominal circumference above the 70th percentile) at diagnosis.

Hypoglycaemic therapy for women with gestational diabetes (which may include regular insulin, rapid-acting insulin analogues [aspart and lispro] and/or oral hypoglycaemic agents [metformin and glibenclamide]) should be tailored to the glycaemic profile of, and acceptability to, the individual woman.
(Note:Â Metformin is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline [www.nice.org.uk/CG063fullguideline]. This evidence is not currently reflected in the SPC [July 2008]. The SPC advises that when a patient plans to become pregnant and during pregnancy, diabetes should not be treated with metformin but insulin should be used to maintain blood glucose levels. Informed consent on the use of metformin in these situations should be obtained and documented).
(Note: Glibenclamide is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline [www.nice.org.uk/CG063fullguideline]. This evidence is not currently reflected in the SPC [July 2008]. The SPC advises that glibenclamide is contraindicated in pregnancy. Informed consent on the use of glibenclamide in pregnancy should be obtained and documented).

Antenatal Care

This section should be read in conjunction with 'Antenatal care: routine care for the healthy pregnant woman' (NICE clinical guideline 62), available from www.nice.org.uk/CG062.

Target Ranges for Blood Glucose during Pregnancy

Individualised targets for self-monitoring of blood glucose should be agreed with women with diabetes in pregnancy, taking into account the risk of hypoglycaemia.

If it is safely achievable, women with diabetes should aim to keep fasting blood glucose between 3.5 and 5.9 mmol/litre and 1-hour postprandial blood glucose below 7.8 mmol/litre during pregnancy.

HbA_{1c} should not be used routinely for assessing glycaemic control in the second and third trimesters of pregnancy.

Monitoring Blood Glucose and Ketones during Pregnancy

Women with diabetes should be advised to test fasting blood glucose levels and blood glucose levels 1 hour after every meal during pregnancy.

Women with insulin-treated diabetes should be advised to test blood glucose levels before going to bed at night during pregnancy.

Women with type 1 diabetes who are pregnant should be offered ketone testing strips and advised to test for ketonuria or ketonaemia if they become hyperglycaemic or unwell.

Management of Diabetes during Pregnancy

Healthcare professionals should be aware that the rapid-acting insulin analogues (aspart and lispro) have advantages over soluble human insulin during pregnancy and should consider their use.

Women with insulin-treated diabetes should be advised of the risks of hypoglycaemia and hypoglycaemia unawareness in pregnancy, particularly in the first trimester.

During pregnancy, women with insulin-treated diabetes should be provided with a concentrated glucose solution and women with type 1 diabetes should also be given glucagon; women and their partners or other family members should be instructed in their use.

During pregnancy, women with insulin-treated diabetes should be offered continuous subcutaneous insulin infusion (CSII or insulin pump therapy) if adequate glycaemic control is not obtained by multiple daily injections of insulin without significant disabling hypoglycaemia. (Note: For the purpose of this guidance, 'disabling hypoglycaemia' means the repeated and unpredicted occurrence of hypoglycaemia requiring third-party assistance that results in

continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.)

During pregnancy, women with type 1 diabetes who become unwell should have diabetic ketoacidosis excluded as a matter of urgency.

During pregnancy, women who are suspected of having diabetic ketoacidosis should be admitted immediately for level 2 critical care, where they can receive both medical and obstetric care. (Note: Level 2 critical care is defined as care for patients requiring detailed observation or intervention, including support for a single failing organ system or postoperative care and those 'stepping down' from higher levels of care.)

Retinal Assessment during Pregnancy

Pregnant women with pre-existing diabetes should be offered retinal assessment by digital imaging with mydriasis using tropicamide following their first antenatal clinic appointment and again at 28 weeks if the first assessment is normal. If any diabetic retinopathy is present, an additional retinal assessment should be performed at 16-20 weeks.

If retinal assessment has not been performed in the preceding 12 months, it should be offered as soon as possible after the first contact in pregnancy in women with pre-existing diabetes.

Diabetic retinopathy should not be considered a contraindication to rapid optimisation of glycaemic control in women who present with a high HbA_{1c} in early pregnancy.

Women who have preproliferative diabetic retinopathy diagnosed during pregnancy should have ophthalmological follow-up for at least 6 months following the birth of the baby.

Diabetic retinopathy should not be considered a contraindication to vaginal birth.

Renal Assessment during Pregnancy

If renal assessment has not been undertaken in the preceding 12 months in women with pre-existing diabetes, it should be arranged at the first contact in pregnancy. If serum creatinine is abnormal (120 micromol/litre or more) or if total protein excretion exceeds 2 g/day, referral to a nephrologist should be considered (eGFR should not be used during pregnancy). Thromboprophylaxis should be considered for women with proteinuria above 5 g/day (macroalbuminuria).

Screening for Congenital Malformations

Women with diabetes should be offered antenatal examination of the four-chamber view of the fetal heart and outflow tracts at 18-20 weeks.

Monitoring Fetal Growth and Well-being

Pregnant women with diabetes should be offered ultrasound monitoring of fetal growth and amniotic fluid volume every 4 weeks from 28 to 36 weeks.

Routine monitoring of fetal well-being before 38 weeks is not recommended in pregnant women with diabetes, unless there is a risk of intrauterine growth restriction.

Women with diabetes and a risk of intrauterine growth restriction (macrovascular disease and/or nephropathy) will require an individualised approach to monitoring fetal growth and well-being.

Timetable of Antenatal Appointments

Women with diabetes who are pregnant should be offered immediate contact with a joint diabetes and antenatal clinic.

Women with diabetes should have contact with the diabetes care team for assessment of glycaemic control every 1-2 weeks throughout pregnancy.

Antenatal appointments for women with diabetes should provide care specifically for women with diabetes, in addition to the care provided routinely for healthy pregnant women (see 'Antenatal care: routine care for the healthy pregnant woman' [NICE clinical guideline 62], available from www.nice.org.uk/CG062). Table 1 in the original guideline document describes where care for women with diabetes differs from routine antenatal care. At each appointment women should be offered ongoing opportunities for information and education.

Preterm Labour in Women with Diabetes

Diabetes should not be considered a contraindication to antenatal steroids for fetal lung maturation or to tocolysis.

Women with insulin-treated diabetes who are receiving steroids for fetal lung maturation should have additional insulin according to an agreed protocol and should be closely monitored.

Betamimetic drugs should not be used for tocolysis in women with diabetes.

Intrapartum Care

This section should be read in conjunction with 'Intrapartum care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55), available from www.nice.org.uk/CG055. This guideline includes information on timing and mode of birth for uncomplicated births at term.

Timing and Mode of Birth

Pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labour, or by elective caesarean section if indicated, after 38 completed weeks.

Diabetes should not in itself be considered a contraindication to attempting vaginal birth after a previous caesarean section.

Pregnant women with diabetes who have an ultrasound-diagnosed macrosomic fetus should be informed of the risks and benefits of vaginal birth, induction of labour and caesarean section.

Analgesia and Anaesthesia

Women with diabetes and comorbidities such as obesity or autonomic neuropathy should be offered an anaesthetic assessment in the third trimester of pregnancy.

If general anaesthesia is used for the birth in women with diabetes, blood glucose should be monitored regularly (every 30 minutes) from induction of general anaesthesia until after the baby is born and the woman is fully conscious.

Glycaemic Control during Labour and Birth

During labour and birth, capillary blood glucose should be monitored on an hourly basis in women with diabetes and maintained at between 4 and 7 mmol/litre.

Women with type 1 diabetes should be considered for intravenous dextrose and insulin infusion from the onset of established labour.

Intravenous dextrose and insulin infusion is recommended during labour and birth for women with diabetes whose blood glucose is not maintained at between 4 and 7 mmol/litre.

Neonatal Care

Initial Assessment and Criteria for Admission to Intensive or Special Care

Women with diabetes should be advised to give birth in hospitals where advanced neonatal resuscitation skills are available 24 hours a day.

Babies of women with diabetes should be kept with their mothers unless there is a clinical complication or there are abnormal clinical signs that warrant admission for intensive or special care.

Blood glucose testing should be carried out routinely in babies of women with diabetes at 2-4 hours after birth. Blood tests for polycythaemia, hyperbilirubinaemia, hypocalcaemia and hypomagnesaemia should be carried out for babies with clinical signs.

Babies of women with diabetes should have an echocardiogram performed if they show clinical signs associated with congenital heart disease or cardiomyopathy, including heart murmur. The timing of the examination will depend on the clinical circumstances.

Babies of women with diabetes should be admitted to the neonatal unit if they have:

- Hypoglycaemia associated with abnormal clinical signs
- Respiratory distress
- Signs of cardiac decompensation due to congenital heart disease or cardiomyopathy
- Signs of neonatal encephalopathy
- Signs of polycythaemia and are likely to needed partial exchange transfusion
- Need for intravenous fluids
- Need for tube feeding (unless adequate support is available on the postnatal ward)
- Jaundice requiring intense phototherapy and frequent monitoring of bilirubinaemia
- Been born before 34 weeks (or between 34 and 36 weeks if dictated clinically by the initial assessment of the baby and feeding on the labour ward)

Babies of women with diabetes should not be transferred to community care until they are at least 24 hours old, and not before healthcare professionals are satisfied that the babies are maintaining blood glucose levels and are feeding well.

Prevention and Assessment of Neonatal Hypoglycaemia

All maternity units should have a written policy for the prevention, detection and management of hypoglycaemia in babies of women with diabetes.

Babies of women with diabetes should have their blood glucose tested using a quality-assured method validated for neonatal use (ward-based glucose electrode or laboratory analysis).

Babies of women with diabetes should feed as soon as possible after birth (within 30 minutes) and then at frequent intervals (every 2-3 hours) until feeding maintains pre-feed blood glucose levels at a minimum of 2.0 mmol/litre.

If blood glucose values are below 2.0 mmol/litre on two consecutive readings despite maximal support for feeding, if there are abnormal clinical signs or if the baby will not feed orally effectively, additional measures such as tube feeding or intravenous dextrose should be given. Additional measures should only be implemented if one or more of these criteria are met.

Babies of women with diabetes who present with clinical signs of hypoglycaemia should have their blood glucose tested and be treated with intravenous dextrose as soon as possible.

Postnatal Care

This section should be read in conjunction with 'Postnatal care: routine postnatal care of women and their babies' (NICE clinical guideline 37, available from www.nice.org.uk/CG037). This guideline include information on the care that all women and babies should receive in the first 6-8 weeks after birth (including information about breastfeeding).

Breastfeeding and Effects on Glycaemic Control

Women with insulin-treated pre-existing diabetes should reduce their insulin immediately after birth and monitor their blood glucose levels carefully to establish the appropriate dose.

Women with insulin-treated pre-existing diabetes should be informed that they are at increased risk of hypoglycaemia in the postnatal period, especially when breastfeeding, and they should be advised to have a meal or snack available before or during feeds.

Women who have been diagnosed with gestational diabetes should discontinue hypoglycaemic treatment immediately after birth.

Women with pre-existing type 2 diabetes who are breastfeeding can resume or continue to take metformin and glibenclamide immediately following birth but other oral hypoglycaemic agents should be avoided while breastfeeding.Â (Note: Metformin is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline [www.nice.org.uk/CG063fullguideline]. This evidence is not currently reflected in the SPC [July 2008]. The SPC advises that metformin is contraindicated in lactation. Informed consent on the use of metformin during lactation should be obtained and documented.) (Note: Glibenclamide is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline [www.nice.org.uk/CG063fullguideline]. This evidence is not currently reflected in the SPC [July 2008]. The SPC advises that there is insufficient/limited information on the excretion of glibenclamide in human or animal breast milk. Informed consent on the use of glibenclamide during lactation should be obtained and documented).

Women with diabetes who are breastfeeding should continue to avoid any drugs for the treatment of diabetes complications that were discontinued for safety reasons in the pre-conception period.

Information and Follow-up after Birth

Women with pre-existing diabetes should be referred back to their routine diabetes care arrangements.

Women who were diagnosed with gestational diabetes should have their blood glucose tested to exclude persisting hyperglycaemia before they are transferred to community care.

Women who were diagnosed with gestational diabetes should be reminded of the symptoms of hyperglycaemia.

Women who were diagnosed with gestational diabetes should be offered lifestyle advice (including weight control, diet and exercise)Â and offered a fasting plasma glucose measurement (but not an OGTT) at the 6-week postnatal check and annually thereafter.

Women who were diagnosed with gestational diabetes (including those with ongoing impaired glucose regulation) should be informed about the risks of gestational diabetes in future pregnancies and they should be offered screening (OGTT or fasting plasma glucose) for diabetes when planning future pregnancies.

Women who were diagnosed with gestational diabetes (including those with ongoing impaired glucose regulation) should be offered early self-monitoring of blood glucose or an OGTT in future pregnancies. A subsequent OGTT should be offered if the test results in early pregnancy are normal (see recommendation in the section "Screening, Diagnosis and Treatment of Gestational Diabetes" above).

Women with diabetes should be reminded of the importance of contraception and the need for pre-conception care when planning future pregnancies.

CLINICAL ALGORITHM(S)

A clinical algorithm for specific antenatal care for women with diabetes is provided in the full version of the original guideline document and in the Quick Reference Guide.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is specifically stated in the evidence review accompanying each recommendation in the full version of the original guideline document.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of diabetes and its complications in women who wish to conceive and those who are already pregnant

POTENTIAL HARMS

Adverse effects of therapies

CONTRAINDICATIONS

CONTRAINDICATIONS

- The British National Formulary recommends that statins should be avoided during pregnancy as congenital malformations have been reported and decreased synthesis of cholesterol may affect fetal development.
- Metformin is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety. This evidence is not currently reflected in the Summary of Product

Characteristics (SPC) (July 2008). The SPC advises that when a patient plans to become pregnant and during pregnancy, diabetes should not be treated with metformin but insulin should be used to maintain blood glucose levels. The SPC also advises that metformin is contraindicated in lactation. Informed consent on the use of metformin in these situations should be obtained and documented.

- Glibenclamide is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety. This evidence is not currently reflected in the SPC (July 2008). The SPC advises that glibenclamide is contraindicated in pregnancy. Informed consent on the use of glibenclamide in pregnancy should be obtained and documented.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any drugs they are considering.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation

The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health'. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

National Institute for Health and Clinical Excellence (NICE) has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (www.nice.org.uk/CG063):

- Slides highlighting key messages for local discussion
- Costing tools:
    - Costing report to estimate the national savings and costs associated with implementation
    - Costing template to estimate the local costs and savings involved
- Audit support for monitoring local practice

Key Priorities for Implementation

Pre-conception Care

- Women with diabetes who are planning to become pregnant should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated.
- The importance of avoiding unplanned pregnancy should be an essential component of diabetes education from adolescence for women with diabetes.
- Women with diabetes who are planning to become pregnant should be offered pre-conception care and advice before discontinuing contraception.

Antenatal Care

- If it is safely achievable, women with diabetes should aim to keep fasting blood glucose between 3.5 and 5.9 mmol/litre and 1-hour postprandial blood glucose below 7.8 mmol/litre during pregnancy.
- Women with insulin-treated diabetes should be advised of the risks of hypoglycaemia and hypoglycaemia unawareness in pregnancy, particularly in the first trimester.
- During pregnancy, women who are suspected of having diabetic ketoacidosis should be admitted immediately for level 2 critical care*, where they can receive both medical and obstetric care.
- Women with diabetes should be offered antenatal examination of the four-chamber view of the fetal heart and outflow tracts at 18-20 weeks.

Neonatal Care

Babies of women with diabetes should be kept with their mothers unless there is a clinical complication or there are abnormal clinical signs that warrant admission for intensive or special care.

Postnatal Care

Women who were diagnosed with gestational diabetes should be offered lifestyle advice (including weight control, diet and exercise) and offered a fasting plasma glucose measurement (but not an oral glucose tolerance test) at the 6-week postnatal check and annually thereafter.

*Level 2 critical care is defined as care for patients requiring detailed observation or intervention, including support for a single failing organ system or postoperative care and those 'stepping down' from higher levels of care.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Mar. 21 p. (Clinical guideline; no. 63).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Mar

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Women's and Children's Health - National Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

Not applicable

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

The Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The Guideline Development Group Members: Dominique Acolet (until October 2007) Clinical Director (Perinatal Epidemiology), Confidential Enquiry into Maternal and Child Health (CEMACH), London; Lynne Carney, Development Officer, Fair Share Trust, Community Foundation for Shropshire and Telford (Lay Representative); Anne Dornhorst, Consultant Physician and Honorary Senior Lecturer in Metabolic Medicine, Hammersmith Hospital, London; Robert Fraser, Reader in Obstetrics and Gynaecology, University of Sheffield; Roger Gadsby, General Practitioner, Nuneaton, and Senior Lecturer in Primary Care, University of Warwick; Jane Hawdon (from October 2007) Consultant Neonatologist, University College Hospitals London NHS Foundation Trust; Richard Holt, Reader of Endocrinology and Metabolism, University of Southampton; Ann Parker, Diabetes Advisory Midwife, Royal Shrewsbury Hospital; Nickey Tomkins, Advanced Nurse Practitioner in Diabetes/Diabetes Specialist Midwife, Medway Primary Care Trust, Kent; Stephen Walkinshaw, Consultant in Maternal and Fetal Medicine, Liverpool Women's Hospital; Jackie Webb, Diabetes Specialist Nurse Manager, Heart of England NHS Foundation Trust, Birmingham; Saiyyidah Zaidi, Programme Manager, Building Schools for the Future, London (Lay Representative)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All Guideline Development Group (GDG) members´ and external advisers´ potential and actual conflicts of interest were recorded on declaration forms provided by the National Institute for Health and Clinical Excellence (NICE) and are presented in Appendix A of the full version of the original guideline document. The forms covered personal pecuniary interests (including consultancies, fee-paid work, shareholdings, fellowships and support from the healthcare industry), personal non-pecuniary interests (including research interests including funding from the healthcare industry for research projects and meetings). The GDG chair and National Collaborating Centre for Women's and Children's Health (NCC-WCH) project director considered all the declarations and concluded that none of the declared interests constituted a material conflict of interest that would influence the recommendations developed by the GDG.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period. Full guideline. London (UK): National Institute for Health and Clinical Excellence; 2008 Mar. 226 p. (Clinical

guideline; no. 63). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

- Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence; 2008 Mar.Â 20 p. (Clinical guideline; no. 63). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Antenatal care. Diabetes in pregnancy. Costing report. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2008 Mar. 51 p. (Clinical guideline; no. 62 and 63). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Antenatal care. Diabetes in pregnancy. Costing template. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2008 Mar. Various p. (Clinical guideline; no. 62 and 63). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Diabetes in pregnancy. Implementing NICE guidance. Slide set. London (UK): National Institute for Health and Clinical Excellence; 2008. 15 p. (Clinical guideline; no. 63). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Diabetes in pregnancy. Audit support. London (UK): National Institute for Health and Clinical Excellence; 2008. 11 p. (Clinical guideline; no. 63). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- The guidelines manual 2007. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 April. Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

  Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1484. 11 Strand, London, WC2N 5HR.

Additional accompanying guideline materials can be found from the National Institute for Health and Clinical Excellence (NICE) Web site.

PATIENT RESOURCES

The following is available:

- Diabetes in pregnancy. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence; 2008 Mar. 24 p. (Clinical guideline; no. 63). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site. Also available in Welsh from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1485. 11 Strand, London, WC2N 5HR.

and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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